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**STATE OF DELAWARE
BOARD OF PHARMACY**

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PUBLIC MEETING NOTICE:	BOARD OF PHARMACY
DATE AND TIME:	Wednesday, September 20, 2017 9:30 am
PLACE:	Conference Room A, 2 nd Floor Cannon Building 861 Silver Lake Blvd., Dover, DE 19904
APPROVED:	November 15, 2017

MEMBERS PRESENT

Susan Esposito, R.Ph., Professional Member, President
Hooshang Shanehsaz, R.Ph., Professional Member, Vice President
Bonnie Wallner, R.Ph., Professional Member
Kimberly Robbins, R.Ph., Professional Member
Tejal Patel, PharmD, Professional Member
Nicholas Juliano, PharmD, Professional Member
Jay Galloway, Public Member
Gayle MacAfee, Public Member

MEMBERS ABSENT

DIVISION STAFF/DEPUTY ATTORNEY GENERAL PRESENT

Eileen Kelly, Deputy Attorney General
Christine Mast, Administrative Specialist III
Michelle McCreary, Pharmacist Compliance Officer
Jason Slavoski, PharmD, Pharmacist Administrator

ALSO PRESENT

John Felton, Appriss
Carolyn Cooper
Michael N Pellagrini
Louis Levenson
John Dinardo
Suzanne Raab-Long
Brian Redding
Meera Patel
Aiyit Daiwani
Tim DeRose
Steve Shipper
Jeanne Chiquione

CALL TO ORDER

Mr. Shanehsaz called the meeting to order at 9:30 a.m.

Mr. Mangler addressed the Board by introducing Jason Slavoski, PharmD, Prescription Monitoring Program (PMP) Administrator for the Division of Professional Regulation and John Felton, Appriss to the Board. The

Appriss Aware migration is scheduled to take place on or about November 7, 2017. Email alerts have been sent to all registrants in the prescription monitoring program (PMP) to the email address of record in the program regarding the migration. There will be 3 notifications in total. Mr. Mangler expressed the importance of reading the notifications and responding to all requests within those notifications to ensure a smooth transition on to the new platform.

REVIEW OF MINUTES

A motion was made by Ms. Patel and seconded by Ms. Esposito to approve the meeting minutes for June 21, 2017. The motion carried.

A motion was made by Ms. Robbins and seconded by Ms. Esposito to table the August 16, 2017 meeting minutes. The motion unanimously carried.

Mr. Shanehsaz publicly thanked Ms. Esposito for all of her hard work and service as President of the Board.

UNFINISHED BUSINESS

Review and Signing of Final Orders

Kodwo Bedu Seyki, R.Ph. – the Board reviewed the Hearing officer recommendation final order and approved the final order. The order was signed by the Board.

Statutory and Regulatory Discussion

Review of Compounding Regulations – a motion to move this topic to the Legislative committee agenda for further review and discussion was made by Ms. Patel and seconded by Ms. Wallner. The motion carried.

Review of 24 Del. C. Sec. 2533 (a) and Regulation 3.6 "Closing of Pharmacy When Pharmacist not Present" – Ms. Kelly stated that there were no changes made to this regulation. This item can be removed from the agenda.

Telemedicine Pharmacy Regulations Changes – Ms. Kelly is preparing the draft proposed regulation changes. This item can be removed from the agenda.

Review and Approval of Proposed Regulations Changes – Ms. Kelly presented the Board with a draft of proposed regulations changes for review. She will prepare these changes for public hearing in January 2018. A motion to approve the proposed regulations was made by Ms. Robbins and seconded by Ms. Esposito. The motion carried. Mr. Shanehsaz will share these changes with the Board of Medical Licensure and Discipline at their next meeting. The Board thanked Ms. Kelly for all of her time and hard work on this effort.

PRESIDENT'S REPORT

Mr. Shanehsaz reported that he attended the bill signing with Governor Carney for the "Addiction Action Committee" at CVS.

NEW BUSINESS

Mr. Shanehsaz read into the record the following ratifications:

Pharmacist and Intern Licensure Approval Ratifications

Pharmacist:

A1-0005097	Samil Jagdishkumar Patel
A1-0005098	William Eli Mattioli
A1-0005099	Maria Fidelis Ilagan Romero
A1-0005100	Indira Beepin Jamnadas
A1-0005101	Willis M. Richardson
A1-0005102	Quynh Ngoc Vu
A1-0005103	Donna M. Rothrock
A1-0005104	Chukwuka S. Dimonye
A1-0005105	Jincy Philip
A1-0005106	Caryn Patricia Robinson

A1-0005107 Stephen Nicholas May
A1-0005108 Khiem Thien Huynh
A1-0005109 Gerald L. Knepp
A1-0005110 Patrick Mensah
A1-0005111 Jamie S. John
A1-0005112 Mason Henry Bucklin
A1-0005113 Ann Lee
A1-0005114 Eugene T. Kwachuh
A1-0005115 James Stanley Young
A1-0005116 Daoud Yousri Tawfik Daoud

A motion was made by Ms. Patel and seconded by Ms. Esposito to approve the ratification of the Pharmacist applications. The motion unanimously carried.

Pharmacist Intern:

A7-0002470 Samil Jagdishkumar Patel
A7-0002471 Darshil D. Patel

A motion was made by Ms. Patel and seconded by Ms. Esposito to approve the ratification of the Pharmacist Intern applications. The motion unanimously carried.

Non-Resident Pharmacy Licensure Approval Ratifications

A9-0002056 Talca Pharmaceuticals, Inc.
A9-0002057 Baxter Healthcare Corporation
A9-0002058 Ardon Health, LLC
A9-0002059 Hillcrest Pharmacy & Compounding of Elkton
A9-0002060 J. Knipper and Company, Inc. dba KnippeRx Inc.
A9-0002061 Foundation Care LLC
A9-0002062 Roadrunner Pharmacy
A9-0002063 Raina Rx LLC dba Route 300 Pharmacy
A9-0002064 Partell Specialty Pharmacy
A9-0002065 RGH Enterprises, Inc. dba Edgepark Medical Supplies
A9-0002066 A & K Pharmacy LLC

A motion was made by Ms. Robbins and seconded by Ms. MacAfee to approve the ratification of the Non-Resident Pharmacy applications. The motion unanimously carried.

Wholesale Distributor Licensure Approval Ratifications

A4-0000244 FFF Enterprises, Inc.
A4-0001682 ALK-Abello, Inc.
A4-0002433 Owens & Minor Distribution, Inc.
A4-0002434 DermaRite Industries, LLC
A4-0002436 Foundation Care LLC
A4-0002437 Global Pharmacy Wholesale
A4-0002439 Unit Dose Solutions, Inc.
A4-0002440 Mercer Medical, LLC
A4-0002441 Marlex Pharmaceuticals, Inc.

A motion was made by Ms. Robbins and seconded by Ms. MacAfee to approve the ratification of the Wholesale Distributor applications. The motion unanimously carried.

Manufacturer

A5-0000072 Marlex Pharmaceuticals, Inc.

A motion was made by Ms. Robbins and seconded by Ms. MacAfee to approve the ratification of the Medical Gas Distributor applications. The motion unanimously carried.

Retail Pharmacy Licensure Approval Ratification

A3-0001013 Saveway Compounding Pharmacy, Inc.

A motion was made by Ms. Robbins and seconded by Ms. MacAfee to approve the ratification of the Retail Pharmacy application. The motion unanimously carried.

Non-Retail Pharmacy Licensure Approval Ratification

None

Outsourcing Facility

AD-0000044 Exela Pharma Sciences, LLC

A motion was made by Ms. Robbins and seconded by Ms. MacAfee to approve the ratification of the Outsourcing Facility application. The motion unanimously carried.

Pharmacist-In-Charge Interviews

A motion was made by Ms. Patel and seconded by Ms. Robbins to amend the agenda to add the following for PIC interview. PIC Michael Bellapigna, CVS #4921, DE. The motion unanimously carried.

Ms. Robbins conducted the Pharmacists in Charge interviews for the following:

PIC - Louis Levenson, Bayhelath Milford, DE

PIC - John Dinardo, Walmart, Middletown, DE

PIC Michael Bellapigna, CVS #4921, DE.

Board Review of Facility Applications

Avita Drugs, LLC. (LA) - a motion was made by Ms. MacAfee and seconded by Mr. Galloway to approve the application. The motion unanimously carried.

PillPack Austin (TX) - a motion was made by Ms. Patel and seconded by Ms. Wallner to table the application. The motion unanimously carried.

Board Review of Pharmacist Applications

None

Continuing Education Review

Kevin Musto - DHSS/DPH - Bioterrorism Awareness & SNS Training 2010 - a motion was made by Ms. Robbins and seconded by Ms. Esposito to approve the course for 3 hours continuing education. The motion unanimously carried.

Pharmacist and Pharmacy - Discussion/Action Items

None

COMMITTEE REPORTS

Legislative – Jay Galloway, Kim Robbins, Tejal Patel, Hooshang Shanehsaz, Bonnie Wallner and Gayle MacAfee

Mr. Shanehsaz appointed Ms. Patel to be Chairperson of the committee going forward. The committee is meeting later today.

Continuing Education – Bonnie Wallner, Tejal Patel:

Ms. Patel stated that the MPJE item writing review was completed. Ms. McCreary and Mr. James Kaminski assisted with this review. Mr. Shanehsaz stated that the next review could be split up among all the members of the Board to assist with this 2000 question project. Ms. Patel stated getting the input of the Board members would create a better pool of questions. Ms. Patel has spoken with test takers who have expressed concern regarding high failure rates for the Delaware examination. Ms. Wallner explained that questions had been removed with multiple answers to assist in reducing confusion.

Consumer Affairs – Jay Galloway, Gayle MacAfee

No Report

Professional Liaisons – Kim Robbins, Tejal Patel and Hooshang Shanehsaz:

Ms. Robbins attended the Delaware Pharmacist Society meeting last evening, where the installation of new officers occurred.

Controlled Substance Liaisons –Tejal Patel, Hooshang Shanehsaz:

Mr. Shanehsaz reported the next meeting of the committee would occur on September 27, 2017.

INSPECTION and PMP REPORT - Michelle McCreary

Ms. McCreary reported the following inspection activities

- 2 – Remodel Inspections
- 2 – Preconstruction Remodel Review of Plans
- 2 – New Construction Review of Plans
- 2 – Complaint Inspections
- 1 – Manufacturer Distributor Inspection
- 1 – Controlled Substance Registration Facility Inspection
- 1 – Drug Enforcement Agency Researcher Inspection
- 2 – Follow up Inspections requiring 7 return visits
- 2 – Ongoing Division Investigation Follow up Inspections

Ms. McCreary is also currently working on numerous change of ownership applications inspections for a community pharmacy corporate entity with many locations.

Ms. McCreary stated she has the following issues to make the Board aware of:

Pharmacist in Charge (PIC) changes occurring and not being reported as required in statute and regulation. She will be following up with locations that she is aware of this occurring. Controlled Substance Act regulation 6.1.5 states: *When a pharmacy relocates to a new building, or there is a change in Pharmacist-in-Charge, a complete audit of all controlled substances must be conducted before the move and within twenty-four hours after the move is complete or the PIC change occurs. If the relocation occurs in the same building, no inventory count shall be required, so long as a pharmacist physically moves the controlled substance inventory.* Ms. McCreary has noted in some cases that this requirement is not being met within the 24 hours of the change of PIC. She has also been made aware that there are instances of the PIC departure and there has been no immediate interim assignment of a PIC. Ms. McCreary stated the PIC Self Inspection report is required to be completed in 30 days however Controlled Substance regulation 6.1.5 stated above must be completed in 24 hours for controlled substances. Ms. Mast stated that the current PIC Change form that is required to be completed when there is a change in PIC could be updated to include this requirement. She would work with the Division in getting this added. Ms. Mast also stated that all facilities are asked during the renewal process to confirm the PIC of record is correct and if changes are required the renewal is placed on hold until the information is provided to the Division.

Ms. McCreary reported that she is continuing to receive complaints regarding regulation 3.8 technician coverage. There is still a lack of technicians as required by this regulation. Many feel that retaliation would occur if they made complaint against their employer. One comment noted by Ms. McCreary “There are not enough mistakes to warrant following the technician regulation”. Ms. McCreary found this comment to be disturbing. Ms. McCreary asked Ms. Kelly about the ability to report complaints anonymously to assist with this issue. Ms. Kelly stated that currently there is no means to investigate anonymous complaints. However, she would review this issue and report back to the Board regarding her findings.

Ms. McCreary stated that currently “ALERTS” from the Drug Diversion Unit are forwarded to the Executive Secretary of the Board which are then forwarded to all pharmacies licensed in this state for distribution. She stated that these alerts should also be sent to all pharmacist and consultant pharmacists as well. Ms. Mast stated that the alerts are sent to the facilities permit holders only because of the number of pharmacists licensed in Delaware are not necessarily practicing in Delaware and the alerts are for Delaware suspicious or fraudulent activity. The facility management receives the alert and then forwards to all locations that could be effected in Delaware.

Ms. McCreary stated that when she had worked on the Multistate Pharmacy Jurisprudence Exam (MPJE) item writing project two years ago NABP asked that “K” questions be removed. They also requested that questions be limited in length so that answers will be limited in length as well. This will make the examination less confusing and more beneficial. Mr. Shanehsaz stated that next year all of the professional members of the Board, as well as Ms. McCreary and Mr. Kaminski can assist with the project. Ms. Kelly stated that the number of Board members included in this process must be limited to protect the integrity and security of the examination. The number of reviewers of this examination should be limited to 3.

Ms. McCreary stated that routine inspections aren't currently scheduled with the current budgeted manpower. Mr. Shanehsaz stated that being reactive is not in the best interest of public safety. Ms. Robbins asked Ms. McCreary if routine inspections are currently being completed. Ms. McCreary stated that current work volume has not allowed her to schedule routine inspections. Mr. Shanehsaz stated that the current budgeted full time equivalent of one compliance officer and work load requirements are not in balance with public safety. Mr. Shanehsaz stated that the Board has noted current workload issues have been expressed to the Division as a concern of the Board.

There has been some discussion with members of the Board by the Division regarding their opinion for the removal of the requirement that the Executive Secretary of the Board be a pharmacist. The Board continues to agree that the Executive Secretary of the Board be required to be a licensed pharmacist in order to support the role of the compliance officer based on the information shared by Ms. McCreary today.

BOARD CORRESPONDENCE

The following correspondence was reviewed by the members of the Board.

NABP So-Called "Canadian" Pharmacies are a Danger to Consumers – This raises many public safety concerns of the Board. The members of the Board will forward this information to state representatives to make them aware.

Safe Biologics - Alliance for Safe Biologic Medicines, this was correspondence sent in an electronic format that could not be shared individually with the Board members. Mr. Shanehsaz will review the media and provide the Board additional information at the next meeting.

OTHER BUSINESS BEFORE THE BOARD

Ms. MacAfee suggested getting complaint/investigation information from the Investigation unit. Ms. Mast will forward the request to Mr. Ford and report back to the Board.

Ms. Patel reported that she attended the NABP Taskforce on Long Term Care. Mr. Shanehsaz stated that Delaware currently has detailed regulations for long term care. She will update the Board as more information becomes available. She also attended the NABP, American Association of College of Pharmacies (AACP) meeting. Next year District I and District 2 will be combined to meet. Deans of Pharmacy Colleges are being invited to attend the meeting in 2018. District II Round table topics discussed were; The Expansion of Pharmacy Technician Roles, Tech Check Tech, Patient Safety Organization (ISMP), Storage/Distribution Drugs Consultation, EPrescribing for Controlled Substances, Pharmacy Robbery Kit (what to do), Time Release Safes for large inventories – limiting quantities of theft.

PUBLIC COMMENT

Mr. Musto provided dates and times of events being held throughout October and November. He will be conducting 3 Bio-Terrorism 3 hour training courses-one in each county. Mr. Musto also expressed concern regarding calls he has received on a weekly basis regarding the return of his expired medications. This is concerning to Mr. Musto in that these drugs may end up in the hands of the public. Mr. Musto asked when PMP updates will resume during the Board meeting. Mr. Shanehsaz stated that the vacant position has been filled and regular updates regarding the PMP should resume next meeting. Mr. Musto also expressed concern regarding the duty to report statute and regulations. Whistle blowers anonymity should be encouraged and protected for the sake of public safety. He suggested that evidence of technician compliance with regulation 3.8 can be accomplished by reviewing pharmacy schedules and payroll information to confirm they are in compliance with regulation 3.8.

NEXT SCHEDULED MEETING

The next meeting is scheduled for October 18, 2017 at 9:30 a.m., 2nd Floor Conference Room.

ADJOURNMENT

There being no other business before the Board, a motion to adjourn the meeting was made by Ms. Patel and seconded by Ms. MacAfee at 12:05 pm. The motion unanimously carried.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Mast". The signature is written in a cursive, flowing style.

Christine Mast
Administrative Specialist III
Liaison, Board of Pharmacy